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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,351	11/26/2003	Wayne D. Comper	62386-043	6164

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,351	COMPER, WAYNE D.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,25-27,29 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,25-27,29 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2007 has been entered. Claims 22, 25-27, 29 and 31-38 are pending and under examination.

Response to Amendment

2. The following objections and rejection are withdrawn:

- The rejection of claims 22, 23 and 25-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot with regard to cancelled claims 23, 28 and 30, and withdrawn with regard to claims 25-27, 29, 31 and 32 in view of Applicant's amendment.
- The rejection of claims 22, 23 and 25-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot with regard to cancelled claims 23, 28 and 30, and withdrawn with regard to claims 25-27, 29, 31 and 32 in view of Applicant's amendment.

Claims Summary and Interpretation

3. The claims are drawn to a method of screening kidney function for the ability to fragment protein in a patient. The steps comprise the following:

- Generate at least one fragmentation profile for at least one protein from a urine sample from the patient.
- Compare the fragmentation profile with a reference fragmentation profile for said at leastone protein of a normal individual.
- Correlate a decrease in fragmentation of the at least one protein with decreased kidney function.

Specifically, the disease is a kidney disease. In one embodiment, the disease causing renal complications is a bacterial infection, congenital defect, stones, allergy or diabetes, such as diabetes mellitus. The decrease in fragmentation is a result of lysosomal dysfunction. The fragmentation profiles are determined in terms of fragment size and sequence. The profile is generated and/or compared to a reference profile using chromatography, electrophoresis, sedimentation or mass spectroscopy, or combinations thereof. The protein that is profiled is albumin or IgG. The profiling is accomplished with HPLC.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(*New Rejection*) Claims 22, 25-27, 29 and 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are summarized above. The specification does not appear to adequately provide support for the new preamble of the claims, "A method of screening kidney function for the ability to fragment protein in a patient". Applicant points to Figures 3, 4 and 6-10, and the paragraph [0075] for support of this amendment. The Office has considered Figures 3, 4 and 6-10, which show fragmentation profiles. However, the Figures do not disclose the screening of kidney function for the ability to fragment protein. The Office has also considered paragraph [75] which is reproduced below:

> **[75] In the method of the invention, albumin is used herein only as an example of a protein to be detected in urine. When the albumin in a patient is analyzed by conventional RIA, it is expected that a normoalbuminuric patient or normal individual would have albumin in the urine in the range of 3-10 μg/min in young people and greater in older people. However, normoalbuminuric patients also show levels of albumin in the urine if measured by HPLC. Applicant has found that these levels may be in the order of 5 μg/min. As kidney disease progresses, the level of intact/modified albumin will increase to microalbuminuria levels in the order of 20 to 200 μg/min as determined by RIA. This will be much higher when determined by HPLC or a method that determines the sum of intact albumin and intact modified albumin. By monitoring the increase in intact/modified albumin, early signs of kidney disease may be detected. However, these levels are not detectable by the methods currently available such as radioimmunoassay using antibodies currently commercially in use, possibly for the reason that antibodies detect certain epitopes. If the albumin is modified in any way as described above, the epitope may be destroyed thereby leaving the modified albumin undetectable.**

Paragraph [75] supports the monitoring of intact/modified albumin to indicate early signs of kidney disease, but is not sufficient to support screening kidney function for the ability to fragment protein in a patient. While the steps in the instant methods are supported in the specification, the overall purpose of the steps (screening kidney function for the ability to fragment protein) does not appear to have been contemplated at the time of filing.

The instant invention is concerned with the fragmentation profiles of proteins as they related to intact modified protein. It is the intact modified protein (initially identifiable by HPLC) that renders the method of monitoring the fragmentation profile novel according to the specification. The phrase "screening kidney function for the ability to fragment protein" is of a broader scope than the initial intent of the specification, which is to monitor intact modified protein via fragmentation profiles. The specification is not directed to overall, general screening of kidney function for the ability to fragment protein. Therefore, the claims are rejected for reciting new matter that was not supported in the specification as originally filed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "condition causing renal complications" lacks antecedent basis in claim 25, from which claim 33 depends. Correction is required.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 6-6-2007
Primary Examiner, TC1600